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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/807,016
Filing Date: March 23, 2004
Appellant(s): FEYGIN ET AL.

Wayne S. Brever
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 8/5/2009 appealing from the Office action mailed 10/6/2008.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

NEW GROUND(S) OF REJECTION

Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cunningham et al. in view of Rosenberg.

Claims 28, 33 & 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cunningham et al./Rosenberg and further in view of Pugh.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

6,654,000	Rosenberg	11-2003
2003/0031993	Pugh	2-2003
6,470,302	Cunningham et al.	10-2002

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1, 4-7, 13-19, 21-25, 28 & 33-40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1 & 2 currently recites "... a first device/second device for performing a first/second skin-interaction technique that is used in conjunction with a simulated vascular-access procedure, wherein the first/second skin-interaction technique is selected from the group consisting of palpation and occlusion and is performed on the pseudo skin at a first skin-interaction region of the pseudo skin, and further wherein:
(a) said receiver and said first device are disposed beneath said pseudo skin and are covered by said pseudo skin ..., Claim 25 currently recites "... a plurality of

mechanisms, wherein said plurality of mechanisms are contained completely within said housing and are covered by said pseudo skin, and wherein said plurality of mechanisms include:

(a) a first mechanism is for simulating a skin-stretch technique that is used in conjunction with a simulated vascular-access procedure and is performed on said pseudo skin ...” and claim 35 currently recites a plurality of mechanisms with which a user interacts for simulating a vascular- access procedure, including at least one mechanism for performing a non-invasive skin interaction technique that is performed on said pseudo skin, wherein said plurality of mechanisms are disposed under said pseudo skin and are covered by said pseudo skin ..”. The examiner is unsure as to how the first device/first mechanism/plurality of mechanism is first used for performing a first skin-interaction technique that is performed on the skin but the first device is disposed beneath the skin.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. **Claim 1, 35 & 38-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenberg (U.S. Patent Number 6,654,000) in view of Pugh (U.S. Publication Number 2003/0031993).**

Referring to claim 1, Rosenberg discloses pseudo skin (barrier 22); a receiver (trocar 24), wherein said receiver receives an end effector (laparoscopic tool 18) through an insertion region in said pseudo skin (column 5 lines 38-47); and a first device (mechanical apparatus 25) for performing a first skin-interaction technique that is used in conjunction with a simulated vascular-access procedure, wherein said receiver and said first device are disposed beneath said pseudo skin and are covered by said pseudo skin (Fig. 1 & column 5 lines 37-56). *Rosenberg does not explicitly disclose a first device for performing a first skin-interaction technique that is used in conjunction with a simulated vascular-access procedure, wherein the first skin-interaction technique is selected from the group consisting of palpation and occlusion and is performed on the pseudo skin at a first skin-interaction region of the pseudo skin and further said insertion region of said pseudo skin is closer to a user than said first skin-interaction region of said pseudo skin when said user is using said apparatus.* However, Pugh teaches a first device (sensors) for performing a first skin-interaction technique (paragraph 0012) that is used in conjunction with a simulated vascular-access procedure (paragraph 0062), wherein the first skin-interaction technique is selected from the group consisting of palpation and occlusion and is performed on the pseudo skin at a first skin-interaction region of the pseudo skin (Fig. 3 and paragraphs 0041 & 0042) and further said insertion region of said pseudo skin is closer to a user than said first skin-interaction region of said pseudo skin when said user is using said apparatus (One region would be closer to a user than another region, depending on the location of the user with respect to the apparatus and paragraph 0044 and it is well known in the art to tie off the vein or

palpate the vein above the insertion point). It would have been obvious to one of ordinary skill in the art at the time the invention was made to include palpation, as disclosed by Pugh, incorporated into Rosenberg in order to check for organs on the organ surface or on the skin.

Referring to claim 35, Rosenberg discloses a pseudo skin (barrier 22); a plurality of mechanisms with which a user interacts for simulating a vascular- access procedure (mechanical apparatus 25 and trocar 24), wherein said plurality of mechanisms are disposed under said skin and are covered by said pseudo skin (column 5 lines 37-56); and a housing (within the "body" of the patient), wherein said housing contains said plurality of mechanisms (Fig. 1 & column 5 lines 37-56). *Rosenberg does not explicitly disclose including at least one mechanism for performing a non-invasive skin-interaction technique that is performed on said pseudo skin.* However, Pugh teaches including at least one mechanism (paragraph 0012) for performing a skin-interaction technique that is performed on said pseudo skin (paragraph 0062). It would have been obvious to one of ordinary skill in the art at the time the invention was made to include palpation, as disclosed by Pugh, incorporated into Rosenberg in order to check for organs on the organ surface or on the skin.

Referring to claim 38, Rosenberg discloses wherein at least one of either a needle or catheter is disposed outside of said housing until inserted therein during a simulated vascular-access procedure (Fig. 1 & the associated text).

Referring to claim 39, Rosenberg discloses further comprising a data processing

system, wherein said data processing system receives signals from sensors that are associated with said plurality of mechanisms (column 10 lines 22-24).

Referring to claim 40, Rosenberg discloses wherein said plurality of mechanisms comprise discrete devices, wherein a first of said devices (column 11 line 47- column 12 line 2) is for enabling a user to perform a skin-stretch technique, a second of said devices (trocar 24) is for receiving a needle or catheter or both, and a third of said devices (column 12 lines 46-49) is for enabling a user to perform at least one of either a palpation technique or an occlusion technique.

5. Claims 4-7 & 13-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenberg/Pugh and further in view of Cunningham et al. (U.S. Patent Number 6,470,302).

Referring to claims 4 & 5, Rosenberg/Pugh discloses the apparatus of claim 1. *Rosenberg/Pugh does not disclose further comprising a second device for performing a second skin-interaction technique on the pseudo skin at a second skin-interaction region of the pseudo skin, wherein said second device is disposed beneath said pseudo skin and is covered by said pseudo skin (claim 4) and wherein: said second skin-interaction technique comprises skin stretching, and said second skin-interaction region of said pseudo skin is closer to a user than said insertion region of said pseudo skin when said user is using said apparatus (claim 5).* However, Cunningham et al. teaches further comprising a second device for performing a second skin-interaction technique on the pseudo skin at a second skin-interaction region of the pseudo skin (column 11 lines 32-54), wherein said second device is disposed beneath said pseudo skin and is

covered by said pseudo skin (Figs. 1-7 & the associated text) (claim 4) and wherein: said second skin-interaction technique comprises skin stretching, (column 11 lines 32-54) and said second skin-interaction region of said pseudo skin is closer to a user than said insertion region of said pseudo skin when said user is using said apparatus (One region would be closer to a user than another region, depending on the location of the user with respect to the apparatus and Figs. 1-7 & the associated text) (claim 5). It would have been obvious to one of ordinary skill in the art at the time the invention was made to include a second device, as disclosed by Cunningham, incorporated into Rosenberg/Pugh in order to stretch the skin to locate the vein.

Referring to claim 6, Rosenberg/Pugh discloses the apparatus of claim 1 and (a) said receiver and said first device are contained within said housing (within barrier 22) and (b) said pseudo skin is substantially co-extensive with a surface of said housing (the same thing so they must be). *Rosenberg/Pugh does not disclose wherein said housing has an anterior portion, a posterior portion, an upper surface and a lower surface wherein, in use: said anterior portion is proximal to a user; said posterior portion is distal to said user; said lower surface is proximal to a support surface on which said apparatus resides; and said upper surface is distal to said support surface.* However, Cunningham et al. teaches said housing has an anterior portion and a posterior portion (Fig. 3); in use, said anterior portion is proximal to a user; and said posterior portion is distal to said user (Fig. 3). It would have been obvious to one of ordinary skill in the art at the time the invention was made to include housing, as disclosed by Cunningham et

al., incorporated into Rosenberg/Pugh in order to protect the receiver and first device from getting damaged.

Referring to claim 7, Rosenberg/Pugh, as modified by Cunningham et al., discloses wherein the upper surface is no more than about 5 inches above the lower surface, the housing units 33 and 40 in Fig. 4 appear to have only a slightly bigger height than the mouse 44. Since a mouse is generally about 1.5 inches high, one could assume that housings 33 and 40 in Fig. 4 are probably about 2 or 3 inches high. Additionally, Pugh discloses that the size of the anatomical simulator and organs represent expected ranges of human size, shape, and other qualities (Paragraph [0038]). Therefore, if the invention were being used to simulate the anatomy of a baby or small child, the height of the anatomical simulator would be less than about 5 inches.

Referring to claim 13, Rosenberg/Pugh, as modified by Cunningham et al., discloses further comprising a second device (paragraph 0012 of Pugh) for performing a second skin-interaction technique on the pseudo skin at a second skin-interaction region of the pseudo skin, wherein said second device is disposed beneath said pseudo skin and is covered by said pseudo skin (paragraphs 0012 & 0013 of Pugh).

Referring to claim 14, Rosenberg/Pugh, as modified by Cunningham et al., discloses wherein: said second skin-interaction technique comprises skin stretch (Figs. 14C, 15 & 16 of Pugh).

Referring to claim 15, Rosenberg/Pugh, as modified by Cunningham et al., discloses wherein at least some portion of said second device is closer to said anterior portion of said housing than said first device (paragraph 0012 of Pugh).

Referring to claim 16, Rosenberg/Pugh, as modified by Cunningham et al., discloses wherein at least some portion of said second device is closer to said anterior portion of said housing than said first end of said receiver (Items 16 & 20 in Fig. 1, paragraph 0037, items 26, 28, 29 & 30 in Fig. 3 & paragraphs 0041 & 0042 of Pugh).

Referring to claim 17, Rosenberg/Pugh, as modified by Cunningham et al., discloses wherein said first end of said receiver is closer to said anterior portion of said housing than said first device (Fig. 4).

Referring to claim 18, Rosenberg/Pugh, as modified by Cunningham et al., discloses wherein an upper-most surface of said first device extends a greater distance above a lowermost surface of said housing than said first end of said receiver (Fig. 2 of Pugh).

Referring to claim 19, Rosenberg/Pugh, as modified by Cunningham et al., discloses wherein an upper-most surface of said first device extends further above a lowermost surface of said housing than an upper-most surface of said second device (Fig. 8 of Pugh).

Referring to claim 21, Rosenberg/Pugh, as modified by Cunningham et al., discloses further comprising an electronics/communications interface, wherein: said electronics/communications interface receives signals from sensors that are associated with at least one of said first device or said receiver (paragraphs 0014-0017 of Pugh); and said electronics/communications interface is disposed beneath said pseudo skin and covered by said pseudo skin (wires located inside simulator of Pugh).

Referring to claim 22, Rosenberg/Pugh, as modified by Cunningham et al., discloses wherein said electronics/communications interface is closer to said posterior portion of

said housing than said first device (depends on the location of the of the simulated organs or sensors with respect to the wires of Pugh).

Referring to claim 23, Rosenberg/Pugh, as modified by Cunningham et al., discloses wherein said electronics/communications interface is closer to said posterior portion of said housing than said receiver (depends on the location of the of the simulated organs or sensors with respect to the wires of Pugh).

Referring to claim 24, Rosenberg/Pugh, as modified by Cunningham et al., discloses wherein said electronics/communications interface comprises a printed circuit board, and further wherein a major surface of said printed circuit board is disposed orthogonal to an uppermost surface of said first device (paragraph 0045 & Item 33 in Fig. 4 of Pugh).

9. Claims 36 & 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenberg.

Referring to claims 36 & 37, Rosenberg et al. discloses the apparatus of claim 35.

Rosenberg does not disclose expressly that the housing is no more than about 4 or 5 inches in height. Instead, Rosenberg indicates using a housing (column 5 lines 54-56).

At the time the invention was made, it would have been obvious matter of design choice to a person of ordinary skill in the art to have the housing having any measurements because Applicant has not disclosed that having adaptive architecture on a second computer provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have

expected Rosenberg's system, and applicant's invention, to perform equally well with the housing taught by Rosenberg or the claimed housing is no more than about 4 or 5 inches in height because both housings would perform the same function of contain the mechanism.

Therefore, it would have been prima facie obvious to modify Rosenberg to obtain the invention as specified in claims 36 & 37 because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art of Rosenberg.

NEW GROUND(S) OF REJECTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cunningham et al. in view of Rosenberg.

Referring to claim 25, Cunningham et al. discloses housing (case 32), wherein said housing has an opening in an uppermost surface thereof (Fig. 3: this opening is not referenced, but the back end of catheter needle assembly (47) and the receiving shaft (44), as depicted in Fig. 4, can be seen emerging from that opening); pseudo skin (Figs. 3 & 7: belt 108 of skin traction mechanism 36) and a plurality of mechanisms are

contained with said housing (Fig. 3) include: (a) a first mechanism is for simulating a skin-stretch technique that is used in conjunction with a simulated vascular-access procedure and is performed on said pseudo skin (skin traction mechanism 36); and (b) a second mechanism for receiving said end effector (receiving shaft 44). *Cunningham et al. does not disclose wherein said pseudo skin covers said opening; wherein said end effector is inserted into said housing through said pseudo skin and wherein said plurality of mechanisms are contained completely within said housing and are covered by said pseudo skin.* However, Rosenberg teaches wherein said pseudo skin covers said opening (column 5 lines 38-47); wherein said end effector (laparoscopic tool 18 with shaft portion 28) is inserted into said housing (within the "body" of the patient) through said pseudo skin (barrier 22, Fig. 1 & the associated text). It would have been obvious to one of ordinary skill in the art at the time the invention was made to include wherein said pseudo skin covers said opening and wherein said end effector is inserted into said housing through said pseudo skin, as disclosed by Rosenberg, incorporated into Cunningham et al. in order to perform a vascular access procedure and allow the manipulation of the laparoscopic tool. *Cunningham et al./Rosenberg does not teach wherein said plurality of mechanisms are contained completely within said housing and are covered by said pseudo skin.* Instead, Cunningham et al. indicates wherein said plurality of mechanisms are contained partially within said housing (Fig. 3 & the associated text) and are partially covered by said pseudo skin (The bottom portion of belt 108 is covered by said pseudo skin. The only portion exposed is the top of the belt 108).

At the time the invention was made, it would have been obvious matter of design choice to a person of ordinary skill in the art to have wherein said plurality of mechanisms are contained completely within said housing and are covered by said pseudo skin because Applicant has not disclosed that having wherein said plurality of mechanisms are contained completely within said housing and are covered by said pseudo skin provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Cunningham's system, and applicant's invention, to perform equally well with either wherein said plurality of mechanisms are contained partially within said housing and are covered by said pseudo skin taught by Cunningham et al. or the claimed wherein said plurality of mechanisms are contained completely within said housing and are covered by said pseudo skin because both said plurality of mechanisms contained within said housing and are covered by said pseudo skin would perform the same function of performing a vascular access procedure.

Therefore, it would have been prima facie obvious to modify Cunningham et al. to obtain the invention as specified in claim 25 because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art of Cunningham et al..

11. Claims 28, 33 & 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cunningham et al./Rosenberg and further in view of Pugh.

Referring to claim 28, Cunningham et al./Rosenberg discloses the apparatus of claim 25 and wherein said end effector is at least one of either a needle or a catheter (needles

and/or catheters). Cunningham et al./Rosenberg does not disclose wherein said mechanisms includes a third mechanism (column 11 line 47 – column 12 line 2) for simulating at least one of a palpation or an occlusion technique that is used in conjunction with a simulated vascular-access procedure and is performed on said pseudo skin, and wherein said end effector is at least one of either a needle or a catheter (column 6 lines 4-13). However, Pugh teaches wherein said mechanisms includes a third mechanism (sensor) for simulating at least one of a palpation or an occlusion technique (paragraph 0012) that is used in conjunction with a simulated vascular-access procedure and is performed on said pseudo skin (paragraph 0062). It would have been obvious to one of ordinary skill in the art at the time the invention was made to include a third mechanism, as disclosed by Pugh, incorporated into Cunningham et al./Rosenberg in order to perform surgical procedures.

Referring to claim 33, Cunningham et al./Rosenberg, as modified by Pugh, teaches wherein said housing has an anterior end and a posterior end (Fig. 3 of Cunningham et al.), wherein in use, said anterior end is proximal to a user; and wherein a portion of said second mechanism is flanked by said first mechanism proximal to said anterior end and said third mechanism proximal to said posterior end (Fig. 3 of Cunningham et al.).

Referring to claim 34, Cunningham et al./Rosenberg, as modified by Pugh, teaches a user interacts with said first mechanism at a first site on said pseudo skin (column 7 lines 32-54 of Cunningham et al.); said user interacts with said second mechanism (25) at a second site on said pseudo skin (punchers skin); said user interacts with said third mechanism at a third site on said pseudo skin (sensors, paragraphs 0012 & 0062); and

locations of each of said first site, second site, and third site on said pseudo skin correspond to locations of said first mechanism, second mechanism, and third mechanism, respectively, within said housing (Pugh discloses that a user may interact with a plurality of simulated organs (i.e., mechanisms) via a plurality of openings on the simulator (Figs. 14A-C, 15, and 16)).

(10) Response to Argument

Ground 1: First, on page 13 of the Arguments the appellant argues the rejection made to claims 1, 4-7, 13-19, 21-25, 28, and 33-40 for being indefinite under 35 USC §112, ¶2 for failing to particularly point out and distinctly claim the subject matter which appellant regards as the invention. Particularly, the appellant states that the language of the claims accurately recites the location of the mechanisms relative to (1) other mechanisms in the device; and/or (2) the pseudo skin; and/or (3) to the housing. The language of the claims also accurately recites the locations on the pseudo skin at which user interacts with each mechanism relative to (1) other mechanisms; and/or (2) the housing; and/or (3) the user. Further stating that one skilled in the art will know that to interact with the palpation mechanism (to practice simulated palpation or occlusion) or to interact with the skin stretch mechanism (to practice a simulated skin stretch technique) simply requires a user to touch his or her fingers to the pseudo skin at the appropriate sites and perform the technique as it would otherwise be performed on a patient. The mechanisms are disposed directly below the resilient skin such that they will function in accordance with their design to enable a user to practice the technique. However, the examiner disagrees with the appellant's assertion because the claims

currently presented is unclear as to how the first device/first mechanism/plurality of mechanisms is first used for performing a first skin-interaction, such as, palpation, occlusion and/or skin-stretching technique which is performed on the skin but the first device/first mechanism/plurality of mechanisms is disposed beneath the skin. The claim language appears to be confusing since first device/first mechanism/plurality of mechanism theses components are beneath the skin but are should to be used on top of the skin for performing palpation, occlusion and/or skin-stretching techniques. Therefore, the appellant still has not proved via the Remarks how this claim language overcomes the 35 USC 112, second paragraph rejection; so the rejection is still upheld by the examiner.

Ground 2: Claim 1: The appellant disagrees with at least allegations (iv)-(vi), which are:
iv)

a first device (mechanical apparatus (25)) for performing a first skin interaction technique; (v) said receiver and said first device are disposed beneath said pseudo skin; and (vi) said receiver and said first device are covered by said pseudo skin. As to allegation (iv), according to Rosenberg, device (25) is a "gimbal apparatus" that "constrains an object that is engaged with the object receiving portion (44) [see FIG. 2] to four degrees of freedom." (Col. 7, lines 50-52.) Figures 3 through 5 depict the manner in which device (25) provides these four degrees of freedom. Figure 6 provides a simplified illustration of the four degrees of freedom. In particular, it shows three rotational degrees of freedom and one translational degree of freedom. In any event, the purpose of gimbal apparatus (25) is not to enable a practitioner to perform a skin

interaction technique (which, in claim 1, is either "palpation" or "occlusion").

As to allegations (v) and (vi), neither the receiver (trocar (24)) nor the first device (apparatus (25)) are disposed beneath pseudo skin (barrier (22)) nor are they covered by it. As depicted in Fig. 1, trocar (24) and apparatus (25) are disposed on one side of barrier (22) and the user is disposed on the other side of it. These distinctions are important, as explained further below. However, the examiner disagrees with the Appellant's assertion because for allegation (iv) the gimbal apparatus 25 is being used for performing a first skin interaction in the broadest sense of the phrase a first skin interaction. A first skin interaction can be any interaction with the skin at this point of the rejection. Also, the appellant using the claim language "for" doing something which is a typical claim language which may not distinguish over the prior art. This is not a positive limitation so the structures only require the ability to so perform which in this case the gimbal apparatus does. For allegations (v) and (vi), the examiner again disagrees because column 5 lines 41-47 & lines 54-57 of Rosenberg specifically state that these components are within the body of the patient. On page 16 of the Arguments, the appellant states that the Examiner admits that Rosenberg does not explicitly disclose a first device for performing a first skin interaction technique wherein: the first skin-interaction technique is selected from the group consisting of palpation and occlusion and is performed on the pseudo skin at a first skin-interaction region of the pseudo skin, and further wherein: (a) ...; and (b) said insertion region of said pseudo skin is closer to a user than said first skin-interaction region of said pseudo skin when said user is using said apparatus. The Examiner alleges, however, that Pugh provides

this missing teaching. In particular, the Examiner alleges that Pugh teaches: (a) a first device (sensors) for performing a first skin-interaction technique (para 0012) that is used in conjunction with a simulated vascular-access procedure (para 0062); (b) wherein the first skin-interaction technique is selected from the group consisting of palpation and occlusion; (c) wherein the first skin-interaction technique is performed on the pseudo skin at a first skin-interaction region (Fig. 3 and paras. 0041 and 0042); and (d) wherein the insertion region is closer to a user than said first skin-interaction region of said pseudo skin when said user is using said apparatus. Appellant disagrees with all of these allegations. As to allegations (a) and (b), the "first device" (sensors) of Pugh is not a device for performing a first skin-interaction technique that is used in conjunction with a simulated vascular-access procedure. Furthermore, although Pugh discloses "palpation" of a blood vessel, in the context discussed, it is neither a "skin-interaction technique" nor performed in conjunction with a simulated "vascular-access procedure." Palpation, as practiced during surgery to discriminate between a tumor and blood vessel, is not a "skin-interaction technique." The "palpation" being referenced in Pugh occurs within the body; that is, directly on the tumor and blood vessel. As such, it is not properly termed a skin interaction technique, since there is no interaction with "skin." This is to be contrasted with palpation as performed in the context of a vascular-access procedure, in which the palpation is performed outside of the body, on the skin of a patient, such as to locate a vein that is not directly observable. The examiner again disagrees with the appellant assertion because in Figs. 12 & 13 show stomach and breast palpation where this palpation takes place outside of surgery. Further, the

appellant uses the claim language "for" doing something which is a typical claim language which may not distinguish over the prior art. This is not a positive limitation so the structures only require the ability to so perform which in this case the sensors do. Next on page 19 of the Arguments, the appellant states that regarding allegation (c), Pugh does not disclose that the first skin-interaction technique is performed on the pseudo skin at a first skin-interaction region. Pugh does disclose palpating organs by pressing on pseudo skin and using a sensor to evaluate palpation pressure, which is disclosed in Pugh at paras. [0041]-[0042] and elsewhere. But, as previously discussed, there is no teaching or suggestion in Pugh to perform a skin-interaction technique used in conjunction with a vascular-access procedure. That is, Pugh provides no teaching pertaining to palpating/occluding a blood vessel by pressing on the surface of the (pseudo) skin at a first skin-interaction region. The examiner again disagrees with the appellant assertion because in Figs. 12 & 13 show stomach and breast palpation where this palpation takes place outside of surgery and Figs. 14B shows the use of a vascular access procedure. The appellant then states on page 19, allegation (d) concerning the relative locations of the "insertion region" and the "skin interaction region" when in use. The Examiner effectively ignores the limitation pertaining to the relative locations of the specific regions, stating, at page 5 of her Official Action, that "One region would be closer to a user than another region, depending upon the location of the user with respect to the apparatus." Indeed it would. When using appellant's device as intended, the relative positions of the user, the insertion region, and first skin interaction region will be correct vis-a-vis the actual procedure. See, for example, FIGs. 3 and 8. With the

device oriented as shown in FIG. 8, the insertion region (334) is closer to the user than the first skin-interaction region (331) for practicing palpation or occlusion. This is the orientation that would be used if someone were performing the actual procedure on a live patient. There is no teaching in the cited art to arrange a simulator in this manner. The examiner disagrees with the appellant assertion because when looking at Fig. 14B, the surgeon's index finger is shown to be further away than the insertion point. It is also well known in the art to tie off the vein or palpate the vein above the insertion point when getting blood drawn. It is also true that the intent of a simulator is for the simulator to perform as close as possible to an actual procedure. The appellant also argues on page 21 that it is inappropriate to combine the teaching of Pugh with Rosenberg. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Rosenberg can indeed be combined with Pugh in order to receive feedback on the performance of the vascular procedures.

Claim 35: Appellant disagrees with at least allegations (iii)-(v). As previously discussed, Rosenberg does not disclose, either in the figures or the disclosure, that a plurality of mechanisms are disposed under barrier (22) or covered by barrier (22). Furthermore,

Rosenberg does not teach or suggest that a housing contains the plurality of mechanisms. In fact, none of the drawings indicate the presence of a housing, nor does the disclosure make any mention of a housing. The barrier is not a housing. The examiner disagrees with the appellant's assertion because column 5 lines 41-47 & lines 54-57 of Rosenberg specifically state that these components are within the body of the patient. The examiner does agree that a barrier is not a housing however, the above cited lines indicate the mechanisms are within the body of the patient which is the housing. Then the appellant argues on page 22 that as previously discussed, Pugh does not teach any mechanism that simulates a vascular- access procedure and that performs a skin-interaction technique, non-invasive or otherwise. (Note that claim 35 requires that the mechanism for performing the non-invasive skin- interaction procedure is one of the mechanisms for simulating a vascular access procedure.) Although Pugh teaches palpation of the skin for conducting abdominal exams, soft tissue exams, etc., Pugh does not teach or disclose a mechanism for performing any skin- interaction technique, including palpation, as it pertains to a vascular access procedure. The examiner again disagrees with the appellant assertion because in Figs. 12 & 13 show stomach and breast palpation where this palpation takes place outside of surgery. Further, the appellant uses the claim language "for" doing something which is a typical claim language which may not distinguish over the prior art. This is not a positive limitation so the structures only require the ability to so perform.

Claims 38-40: The Appellant argues on page 23 that neither Rosenberg nor Pugh nor the combination thereof disclose or suggest a device that enables a user to perform "a

skin-stretch technique," which is the third of the three skin interaction techniques that appellant's simulator is capable of enabling a user to practice. the appellant uses the claim language "for" doing something which is a typical claim language which may not distinguish over the prior art. This is not a positive limitation so the structure only requires the ability to so perform.

Ground 3: Claims 4 & 5: As already discussed, neither Rosenberg nor Pugh disclose "a first skin interaction technique that is used in conjunction with a vascular-access procedure." That being the case, Cunningham cannot disclose a second such technique. Cunningham, in fact, discloses a rudimentary skin stretching mechanism, as depicted in FIG. 3 (skin traction mechanism (36) and casing (127) and FIG. 7 (showing the details of the mechanism). But this is the only skin-interaction technique that Cunningham teaches; it provides no mechanisms for practicing palpation or occlusion. And that omission in and of itself is telling. Since Rosenberg and Pugh do not teach "a first device for performing a first skin-interaction technique that is used in conjunction with a simulated vascular-access procedure" and since Cunningham only discloses a single skin-interaction technique (skin stretch), the combination of these references do not disclose all the limitations of claims 4 or 5. The examiner disagrees with the appellant's assertion and for the sake of brevity has decided not reiterate the reasons. Please see Remarks made by the examiner in regards to claim 1. Also, claim 5 positively recites the claimed language whereas in claim 4 the argued limitations are not positively recited. Since, there is a first skin interaction technique is proving to exist in

the prior art, Cunningham can disclose a second such technique which has been mapped to column 11 lines 32-54 of Cunningham et al..

Claims 6 & 7: Next on the bottom of page 24, the appellant states as already discussed, the combination of Rosenberg and Pugh does not disclose the claimed "first device" (for performing a first skin-interaction technique that is used in conjunction with a simulated vascular-access procedure, wherein the first skin-interaction technique is selected from the group consisting of palpation and occlusion) nor does the combination of these references disclose that the receiver and non-existent first device are "contained in said housing." The examiner disagrees with the appellant's assertion and for the sake of brevity has decided not reiterate the reasons. Please see Remarks made by the examiner in regards to claim 1. On page 25, the appellant then states that the Examiner argues that the "barrier (22)" of Rosenberg is a housing. Yet, barrier (22) houses nothing; it is a partition. Furthermore, the Examiner alleges that the pseudo skin is substantially co-extensive with a surface of said housing, as per limitation (b) of claim 6. In this case, the examiner does agree with the appellant that the barrier 22 is not a housing but a partition. However, as previously noted the housing is within the body of the patient. Next the appellant states that as previously indicated, the only device disclosed in Cunningham that pertains to a skin-interaction procedure is skin traction mechanism (36). Regarding claim 6, the skin traction mechanism (36) does not meet the limitations of "the first device" because it does not enable a user to perform palpation or occlusion (as required per base claim 1). Furthermore, skin traction mechanism (36) resides in its own casing (127). Claim 6 requires both the "receiver"

and the "first device" to reside within the housing, which in the Cunningham is "case (32)." Clearly, the skin traction mechanism does not reside in case (32). In this case, the examiner disagrees with the appellant's assertion and for the sake of brevity has decided not reiterate the reasons. Please see Remarks made by the examiner in regards to claim 1. Additionally, Cunningham et al. was not used to teach "the first device" or the "receiver". Rosenberg disclosed these components as wherein "the first device" is the mechanical apparatus 25 and the "receiver" is the trocar 24 which are both within the body of the patient that maps to the housing.

Next, Regarding claim 7, the appellant states that neither Rosenberg nor Pugh disclose a "housing." Cunningham does. Although the reference itself is silent on size, as previously noted, appellant was in possession of the device disclose in Cunningham. The housing was bigger than five inches, top to bottom. The examiner disagrees with the appellant assertion because the housing has been mapped to being within the body of the patient of Rosenberg and as far as size is concern, the specs of the housing is a mere design consideration which fails to patentably distinguish over the prior art. Next the appellant states that claims 13 adds the limitation, to claim 6, of a second device for performing a second skin- interaction technique, wherein the second device is disposed beneath and covered by the pseudo skin. This claim thus recites two devices for performing different skin-interaction techniques, and wherein both are within the housing (since there are disposed beneath and covered by the pseudo skin). The combination of Rosenberg, Pugh, and Cunningham does not disclose these limitations. The examiner disagrees with the appellant's assertion because these limitations are not

positively recited, therefore the structure only so has to be capable of performing the function. In this case, paragraphs 0012 & 0013 of Cunningham et al. teaches the limitation of concern. Claims 14-19 are all dependent on claim 13 are rejected for the same reasons and rationale.

Ground 4: Claim 25: A new grounds of rejection has been made for this claim addressing the argued allegations. See rejection above.

Ground 5: Claim 28: As already discussed, the appellant states that neither Cunningham, Rosenberg or Pugh disclose a mechanism for simulating a palpation technique or an occlusion technique that is used in conjunction with a simulated vascular-access procedure. However, the examiner disagrees with the appellant's assertion for the mere fact that this claim limitation is not positively recited so in stating that fact the structures requirement is that it must have the ability to perform. In this case, Pugh teaches the claimed limitation.

Claim 33: The appellant asserts that claim 33 recites the positioning of the three mechanisms (skin stretch, receiver, and palpation/occlusion) relative to one another within the housing. This arrangement is not taught or suggested by the Cunningham, Rosenberg, or Pugh and, therefore, claim 33 is not obvious in view of these references. The examiner asserts that in this case it is believed true that the housing (within the body of the patient) has anterior end (front of body) and a posterior end (back of body).

Ground 6: Claim 34: The examiner asserts in Rosenberg, the end effector is NOT inserted through the pseudo skin during the performance of the simulated vascular-access procedure. (And there is no "housing" disclosed.). However, the examiner

disagrees because the laparoscopic tool has a shaft that is inserted through the pseudo skin during the performance of the simulated vascular-access procedure of Rosenberg. Rosenberg does disclose a housing which maps to being within the body of the patient. Next, the appellant argues that in the apparatus of Pugh, no provision for simulating a skin stretch (first mechanism) or palpation/occlusion (third mechanism) in conjunction with a vascular-access procedure is provided. Furthermore, to the extent that Pugh mentions palpating a tumor to distinguish it from a blood vessel, this is done when the "body cavity" is open, as previously discussed; palpation is not performed on pseudo skin (to locate an invisible underlying vessel). Furthermore, Pugh provides no disclosure of a second mechanism; that is, the user does not interact with the receiver at a site on any pseudo skin. The examiner once again disagrees with the appellant's assertion because Cunningham teaches skin-stretch via skin traction mechanism 36. Also in Figs. 12 & 13, the stomach and breast are palpated which occurs outside the body. Lastly, the appellant argues that as a consequence, there is no support for the Examiner's contention that the combination of Cunningham, Rosenberg, and Pugh teach interacting with the first, second, and third mechanisms at respective first, second, and third sites on pseudo skin. Nor is there any disclosure or suggestion in the prior art that the locations of those sites should correspond to the relative position of the mechanisms within the housing. The examiner disagrees with the appellant's assertion because each interaction with the mechanisms occur at different sites and that Pugh discloses that a user may interact with a plurality of simulated organs (i.e. mechanisms) via a plurality of openings on the simulator (Figs. 14A-C, 15 & 16). In addition this claim

depends from claim 28 so the same rationale, remarks and rejections apply here as well.

Ground 7: Claims 36 & 37: These claims are dependent on claim 35 therefore; the same rejection, remarks and rationale applies to these claims.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

This examiner's answer contains a new ground of rejection set forth in section (9) above. Accordingly, appellant must within **TWO MONTHS** from the date of this answer exercise one of the following two options to avoid *sua sponte* **dismissal of the appeal** as to the claims subject to the new ground of rejection:

(1) **Reopen prosecution.** Request that prosecution be reopened before the primary examiner by filing a reply under 37 CFR 1.111 with or without amendment, affidavit or other evidence. Any amendment, affidavit or other evidence must be relevant to the new grounds of rejection. A request that complies with 37 CFR 41.39(b)(1) will be entered and considered. Any request that prosecution be reopened will be treated as a request to withdraw the appeal.

(2) **Maintain appeal.** Request that the appeal be maintained by filing a reply brief as set forth in 37 CFR 41.41. Such a reply brief must address each new ground of

rejection as set forth in 37 CFR 41.37(c)(1)(vii) and should be in compliance with the other requirements of 37 CFR 41.37(c). If a reply brief filed pursuant to 37 CFR 41.39(b)(2) is accompanied by any amendment, affidavit or other evidence, it shall be treated as a request that prosecution be reopened before the primary examiner under 37 CFR 41.39(b)(1).

Extensions of time under 37 CFR 1.136(a) are not applicable to the TWO MONTH time period set forth above. See 37 CFR 1.136(b) for extensions of time to reply for patent applications and 37 CFR 1.550(c) for extensions of time to reply for ex parte reexamination proceedings.

Respectfully submitted,

/K. F./

Examiner, Art Unit 3715

A Technology Center Director or designee must personally approve the new ground(s) of rejection set forth in section (9) above by signing below:

/Robert P Olszewski/

Director, Technology Center 3700

Conferees:

/XUAN M. THAI/

Supervisory Patent Examiner, Art Unit 3715

/Gene Kim/

Supervisory Patent Examiner, Art Unit 3711